

RESPONSE TO RESTRICTION REQUIREMENT OF JUNE 21, 2005

Sir:

Applicant provides the following election in response to the Restriction Requirement dated June 21, 2005, in the above-captioned application. The Office Action of June 21, 2005, set forth restriction under 35 U.S.C. § 121 to purportedly distinct inventions. Applicant hereby provisionally elects **Group 3** (claims 39-47 and 53), drawn to polypeptides encoded by single nucleotide polymorphisms (SNPs) and therapeutic agents comprising polypeptides encoded by SNPs with **traverse**. Applicant hereby provisionally elects **Group J**, drawn to g798c SNP, with **traverse**. Applicant hereby provisionally elects **Group O**, drawn to polypeptides encoded by SNPs leading to the amino acid change C122S, with **traverse**. Applicant reserves the right to file divisional application(s) directed to non-elected subject matter. Applicant notes that the Office Action contains a typo on page 8 line 10, "C112S" should be "C122S". Applicant made its election based on "C122S" as recited in claim 34.

REMARKS

The Office Action requires that Applicant elect one Group from three Restriction Requirements: one Group from Group 1-6; one Group from Groups A-K; and one Group from Groups M-O. Applicant respectfully requests reconsideration of the Restriction Requirement in view of the following remarks concerning the elections made herein.

The restriction between inventions is only proper when a search burden exists for the Examiner to search all of the inventions claimed. If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. See MPEP §803.01.

In the instant case, Groups 1, 3, and 4 are drawn to the interferon α -5 nucleic acid, polypeptide, and antibodies thereof. The interferon α -5 nucleic acid (SEQ ID NO: 1) encodes for the interferon α -5 polypeptide which in turn is the target of the antibody, thus all three Groups inexorably linked by structure and function. Therefore, does not constitute a search burden to search for a single nucleic acid which encodes a single polypeptide, as searching for one will lead to the other. See MPEP §803.04. In addition, Groups 1 and 2 share the same class (435), Groups 3 and 4 share the same class (530), and Groups 5 and 6 share the same class and subclass (514/2). It is evident from overlapping subject matter and overlapping class/subclass

that a search of the subject matter of Groups 1, 2, 3, 4, 5, and 6 does not constitute a serious search burden for the Examiner.

Further, the Office Action did not elucidate reasons and examples as required by MPEP §803 to support restriction between eleven SNPs in the interferon α -5 nucleic acid: c42t, g43a, c82t, a123t, g152c, t174c, g292c, a516g, c641g, g798c, and g1009a. All eleven SNPs occur in the same gene and all eleven SNPs are instantly claimed in reference to a single nucleic acid sequence (SEQ ID NO: 1). See MPEP §803.04. In *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980), the court held that unity of invention exists where compounds included within a Markush group: (a) share a common utility and (b) share a substantial structural feature disclosed as being essential to that utility. In the instant case, all of the members of the group are the same save for a single nucleotide polymorphisms. Therefore, they all share a common utility and share a substantial structure feature as they all are derived from the same nucleic acid. Thus the eleven SNPs share a common structure and function and it is inappropriate to restrict between the eleven SNPs.

Additionally, the Office Action did not elucidate reasons and examples as required by MPEP §803 to support restriction between three SNPs in the interferon α -5 polypeptide: Q28R, Q70E, and C122S. All three SNPs occur in the same protein and all three SNPs are instantly claimed in reference to a single amino acid sequence (SEQ ID NO: 2). See MPEP §803.04. In *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980), the court held that unity of invention exists where compounds included within a Markush group: (a) share a common utility and (b) share a substantial structural feature disclosed as being essential to that utility. In the instant case, all of the members of the group are the same save for a single nucleotide polymorphisms (encoding for a point mutation in the polypeptide). Therefore, they all share a common utility and share a substantial structure feature as they all are derived from the same amino acid sequence. Thus the three SNPs share a common structure and function and it is inappropriate to restrict between the three SNPs.

In view of the above remarks, Applicant respectfully requests that the Restriction Requirement be withdrawn and that all claims be prosecuted in the same patent application. At the least, Applicant respectfully requests rejoinder of Groups 1 and 3. In the event that the requirement is made final and in order to comply with 37 C.F.R. § 1.143, Applicant reaffirms the election with **traverse** of Group 3 (claims 39-47 and 53), Group J (g798c SNP), and Group O

(C122S SNP), holding claims 1-38, 48-52, and 54-56 in abeyance under the provisions of 37 C.F.R. § 1.142(b) until final disposition of the elected claims.



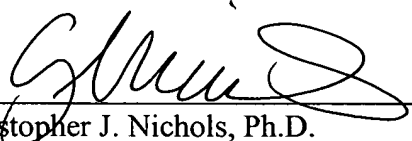
CONCLUSION

Applicant maintains that the restriction requirement is improper and that all pending claims, *i.e.*, claims 1-56, should be examined for patentability. If the Examiner believes that prosecution might be advanced by discussing the application with Applicant's representatives, in person or over the telephone, we would welcome the opportunity to do so.

Respectfully submitted,

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